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By electronic mail to: http://www.fda.gov/docket/ecomments

October 4, 2004

Food and Drug Administration
Division of Docket Management
5630 Fishers Lane
Room 1061
Rockville MD 20852

Attn: Philip L. Chao, Office of Policy and Planning (HF-23)

SUBJECT: Food and Drug Administration
Institutional Review Boards: Registration Requirements
Docket No. 2004N-0242

Dear Mr. Chao:

The Council on Governmental Relations (COGR) is an association of 150 research intensive universities, affiliated hospitals and research institutes in the United States. COGR works with federal agencies to develop a common understanding of the impact that federal policies, regulations and practices may have on the research conducted by the membership. Our member universities, academic medical centers, and affiliated hospitals conduct a significant proportion of the clinical research regulated by the Food and Drug Administration (FDA) either as the principal investigator for a clinical trial or as one of multiple sites in an industry-sponsored trial.

Institutional review boards (IRBs) play a pivotal role in ensuring the health and well being of the participants in human subject research. As such, it is appropriate that the HHS maintain accurate information about the IRBs that approve and monitor FDA-regulated clinical investigations and HHS-supported research. The information collection proposed for 56.106 (a) – (b) (1)-(4) is narrowly defined to identify IRBs reviewing FDA-regulated clinical investigations under section 505(i) or 520(g) of 21 CFR 56 and meets the current IRB member identification requirements at 21 CFR 56.107 and 56.115(a)(5). These proposed data elements are an appropriate part of the IRB registration and institutional assurance processes.

We caution the FDA that the proposed data collection outlined at §56.106 (b)(3) and (4) will provide the FDA with information whose value is limited to the very narrow purposes defined in the proposed collection – identification of IRBs that review FDA regulated products. It would be

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more appropriate for the FDA to ask the simple question, does the IRB review protocols dealing with FDA-regulated products, including clinical investigations supporting research or marketing permits, or not. This type of question will reduce the reporting burden while still helping to identify those institutions involved in FDA regulated research activities. The FDA request for the approximate number of active protocols involving FDA regulated products reviewed in the preceding calendar year suggests that the number of FDA protocols being reviewed is a reasonable basis for determining a IRBs activity level. Protocols are neither uniform nor uniformly complex. For example, twenty-four investigational new drug clinical trials will most likely generate a significantly greater volume of work than five hundred social or statistical data analyses for marketing permits. Because FDA appropriately limits its request for protocol data to studies regulated by the FDA, this limited data set further undermines the value of the proposed data collection for assessing IRB activity level. Any use of these data beyond simple identification would be inappropriate.

The additional request for general or generic descriptions of the types of FDA-regulated products, e.g., drugs, biological products, etc., is appropriate only if it is used for the purpose of sending useful and targeted information. The requirement should be limited to a simple generic description without numerical ranges associated with a specific product type.

Finally, the names of accredited institutions and organizations are available from the accrediting bodies. If FDA believes that it is useful to know which organizations and institutions have been accredited, it may contact these accrediting bodies directly or review the lists provided online at the organizations' web sites. Since this information is publicly available, the additional reporting burden – no matter how small – should not be passed on to the institution. In fact, the websites will present more up-to-date information than the HHS database because changes in accreditation status would be reported during the three-year registration renewal process. In response to the question posed in the notice, we do not believe that the accreditation status of an institution considered individually or collectively will provide FDA with new information that will prove useful in assessing the value of that accreditation.

We note the effort by FDA and the Office for Human Research Protections (OHRP) to create a single HHS site for IRB registration. This simplification and streamlining for IRB registration is much appreciated.

We note that because FDA regulations require sponsors and investigators to comply with part 56 or use an IRB that complies with part 56, the FDA proposes to consider sponsors and investigators to be in compliance with their regulatory obligations if, and only if, they use a registered IRB. This approach is sufficient to require the use of registered IRBs. Any additional sanctions or administrative mechanisms will only serve to increase the burden on sponsors, investigators, and IRBs without adding to the protection of subjects.

In summary, we strongly recommend that prior to finalizing the proposed rules on IRB Registration Requirements, FDA revise the proposed § 56.106 (b)(3) to a simple, yes/no question and eliminate the request for accreditation information in proposed § 56.106 (b) (5). Collecting data for the purposes of identifying IRBs reviewing FDA regulated products has limited value and must be used within those limits. Any additional data collections increase the burden on the reporting organizations without measurably adding to the protection of human subjects. It drains resources at research institutions and at FDA that we believe should be directed at activities that will better protect human research subjects.

We appreciate the opportunity to comment.

Sincerely,

Katharina Phillips

Katharina Phillips
President